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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,020	10/10/2000	Jennifa Gosling	19934000710	4696

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EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/686,020	Applicant(s) GOSLING ET AL.	
	Examiner Bridget E. Bunner	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-48* is/are pending in the application.

4a) Of the above claim(s) *38-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-37 and 44-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *33-48* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12,13*.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election of the species ELC and inflammation in Paper No. 19 (27 January 2003) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 38-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 19 (27 January 2003).

It is noted to Applicant that upon allowance of the elected species, applicant will be entitled to consideration of claims to additional species until all species have been examined or a non-allowable species is found.

Claims 33-37 and 44-48 are under consideration in the instant application, as they read upon the species of ELC and inflammation.

Drawings

1. The formal drawings were received on 27 January 2003 (Paper No. 18). These drawings are acceptable.

Specification

2. The disclosure is objected to because of the following informalities:

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. (See pg 13, line 31; pg 51, lines 23-24; pg 53, line 22)

Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

4. The Brief Description of Drawings for Figure 4 at pg 5-6 of the specification does not refer to Figure 4A.

Appropriate correction is required.

Claim Objections

5. Claims 33-37 and 47-48 are objected to because of the following informalities:

5a. Claims 33-37 and 47-48 recite non-elected species.

5b. Claim 33, line 1 recites "treating an CCX CKR-mediated condition". However, to be more grammatically correct, the claim should be amended to recite "treating a CCX CKR-mediated condition".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 33-37 and 44-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, the claims are directed to a method of treating an CCX CKR-mediated condition in a mammal comprising administering to the mammal an agent that inhibits or

promotes the binding of CCX CKR to ELC (EBI-1-ligand chemokine) in a cell or tissue in the mammal. The claims also recite that the CCX CKR-mediated condition is inflammation. The claims recite that the mammal is a human or non-human primate and that the agent is an antibody.

The specification of the instant application teaches "methods of treating CCX CKR-mediated conditions or diseases by administering to a subject having such a disease or condition, a therapeutically effective amount of a modulator of CCX CKR function, i.e., agonists (stimulators) and antagonists (inhibitors) of CCX CKR function or gene expression. Such modulators include small molecules agonists and antagonists of CCX XKR function; polypeptide inhibitors; antisense, ribozyme, and triplex polynucleotides; gene therapy, and the like" (pg 39, lines 1-9). The specification also teaches the modulators CCX CKR activity can inhibit the proliferation and differentiation of cells involved in an inflammatory response (pg 39, lines 30-31). However, this prophetic procedure is not adequate guidance, but is merely an invitation for the artisan to use the current invention as a starting point for further experimentation. For example, the prophetic example does not teach the skilled artisan the optimal dosage, duration, and mode of administration of any agent to any mammal. Furthermore, the claimed method may not necessarily treat a CCX CKR-mediated condition, such as inflammation. The skilled artisan must resort to trial and error experimentation to determine the optimal dosage, duration, and mode of administration of all possible agents that inhibit or promote binding of CCX CKR to ELC. Such trial and error experimentation is considered undue. According to MPEP § 2164.06, "the guidance and ease in carrying out an assay to achieve the claimed objectives may be an issue to be considered in determining the quantity of experimentation needed."

Additionally, the specification does not disclose any conditions that are specifically associated with altered levels or forms of the CCX CKR. The specification also does not identify a CCX CKR-mediated condition that has the binding of CCX CKR to ELC as a rate limiting step. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Furthermore, there are no agents disclosed that interrupt or otherwise modulate binding of CCX CKR to ELC. Therefore, the specification does not provide enabling guidance regarding how to select an agent or patient.

The specification teaches that CCX CKR is internalized in the presence of ELC, SLC, TECK, and CTACK (pg 59, Example 8). However, there are also no methods or working examples in the specification indicating the mechanism of action required by the agent for treatment of a CCX CKR-mediated condition. For example, in order to treat a CCX CKR-mediated condition, does the agent inhibit the binding of the ligands to the receptor and therefore, inhibit internalization? Or, does the agent promote the binding of the ligands to the receptor and therefore, promote internalization of the receptor? Since the specification does not associate a specific condition with CCX CKR, undue experimentation would be required of the skilled artisan to identify such a disease and determine whether to inhibit the binding of the ligands (such as ELC) to the receptor or to promote the binding of the ligands to the receptor.

Due to the large quantity of experimentation necessary to identify a CCX CKR-mediated condition that requires the binding of CCX CKR to ELC as a rate limiting step, to identify individuals with a CCX CKR-mediated condition, to identify and administer agents that would inhibit/promote binding of CCX CKR to ELC and treat the condition, and to determine the mechanism of action of the agent (i.e., inhibition or promotion), the lack of direction/guidance

presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, and the breadth of the claims which fail to recite limitations on a specific CCX CKR-mediated condition and the mechanism of action of the agent necessary for treatment of that condition, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

7. Claims 33-37, 44-45, and 47-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the claims are directed to a method of treating an CCX CKR-mediated condition in a mammal comprising administering to the mammal an agent that inhibits or promotes the binding of CCX CKR to ELC (EBI-1-ligand chemokine) in a cell or tissue in the mammal. The claims also recite that the CCX CKR-mediated condition is inflammation. The claims recite that the mammal is a human or non-human primate and that the agent is an antibody.

As discussed above, the specification only teaches "methods of treating CCX CKR-mediated conditions or diseases by administering to a subject having such a disease or condition, a therapeutically effective amount of a modulator of CCX CKR function, i.e., agonists (stimulators) and antagonists (inhibitors) of CCX CKR function or gene expression. Such modulators include small molecules agonists and antagonists of CCX XKR function; polypeptide inhibitors; antisense, ribozyme, and triplex polynucleotides; gene therapy, and the like" (pg 39,

lines 1-9). However, the specification does not teach any specific agents that are capable of inhibiting or promoting the binding of CCX CKR to ELC to treat a CCX CKR-mediated condition. The brief description in the specification of a few examples of agents that could be administered to an individual is not adequate written description of an entire genus of agents, both organic and inorganic.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

The skilled artisan cannot envision the infinite number of agents encompassed by the claimed methods, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The agents itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class.

Therefore, only a specific agent, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath*

makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

35 USC § 112, second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 33-37 and 44-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Regarding claims 33-37 and 44-48, the acronym "CCX CKR" renders the claims vague and indefinite. Abbreviations should be spelled out in all independent claims for clarity.

11. Claims 33-37 and 44-48 are indefinite because the claims do not have a step that clearly relates back to the preamble. For example, there is no step indicating that administration of an agent treats a CCX CKR-mediated condition.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

BEB
Art Unit 1647
April 11, 2003

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER